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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

ELAINE SPLAN, an Individual;

Plaintiffs,

vs.

COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC.; COOK INCORPORATED; COOK GROUP, INC.; and WILLIAM COOK EUROPE APS; DOE PROMOTER; DOE SALES REPRESENTATIVE; and DOES I through X, inclusive; and ROE BUSINESS ENTITIES XI through XX, inclusive,

Defendants.

CASE NO.

COMPLAINT
AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff, ELAINE SPLAN, by and through her attorneys, PETER S. CHRISTIANSEN, ESQ., R. TODD TERRY, ESQ., and KEELY A. PERDUE, ESQ. of CHRISTIANSEN LAW OFFICES and for her causes of action against Defendants, and each of them, allege as follows:

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THE PARTIES

1. At all times relevant to this action, Plaintiff Elaine Splan was and is a resident of Clark County, Nevada. In August 2012, she underwent placement of a Cook Gunther Tulip Inferior Vena Cava Filter. This device subsequently failed and perforated through her vena cava, abutting her pancreas and duodenum. The device remains permanently in Plaintiff's body.

2. Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. regularly conducts business in the state of Nevada and is authorized to do so.

3. Defendant Cook Incorporated is the parent company of Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant Cook Incorporated regularly conducts business in the state of Nevada and is authorized to do so.

4. Defendant Cook Group, Inc. is the parent company of Defendant Cook Medical Incorporated and Cook Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group, Inc. regularly conducts business in the state of Nevada and is authorized to do so.

5. Defendant William Cook Europe APS is based in Bjaeverskov, Denmark and regularly conducts business in the state of Nevada and is authorized to do so.

6. At all times relevant to this action, upon information and belief, Defendants Doe Promoter and/or Doe Sales Representative were in the business of marketing, distributing, advocating, and selling the Cook Gunther Tulip Inferior Vena Cava Filter utilized by Plaintiff's health care providers and which was implanted in Plaintiff.

7. Hereinafter, each of the above defendants shall be collectively referred to as "Cook."

8. At all times alleged herein, Defendants Cook include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their offices,

directors, employees, agents, representatives and any and all other persons acting on their behalf.

9. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology, and surgical products throughout the United States and around the world. Cook's products include the Cook Gunther Tulip Inferior Vena Cava Filter, which is used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

10. This Court has jurisdiction over the subject matter of this action and the parties. This Court is also the proper venue for this action.

11. That the true names and capacities, whether individual, corporate, association or otherwise of the Defendant, DOES I through X and/or ROE BUSINESS ENTITIES XI through XX, are unknown to Plaintiff at this time. Plaintiff is informed and believes, and thereupon allege, that each of the Defendant designated herein as DOES and/or ROES BUSINESS ENTITIES were involved in the initiation, approval, support or execution of the wrongful acts upon which this litigation is premised, or of similar actions directed against Plaintiff about which she is presently unaware. These defendants are responsible in some manner for the events and happenings herein referred to, and in some manner caused the injuries and damages proximately thereby to the Plaintiff, as herein alleged; that the Plaintiff will ask leave of this Court to amend this Complaint to insert the true names and capacities of said Defendants, DOES I through X and/or ROE BUSINESS ENTITIES XI through XX inclusive, when the same have been ascertained by Plaintiff, together with the appropriate charging allegations, and to join such Defendant in this action.

12. All defendants shall be referred to hereinafter collectively as Defendants.

STATEMENT OF VENUE AND JURISDICTION

13. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), including interests and costs.

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14. Venue is proper in this Court under 28 U.S.C. § 1391, as a substantial part of the events or omissions giving rise to the claim occurred within this District and the Defendants regularly conduct business in this District.

FACTUAL BACKGROUND

15. Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell products such as IVC filters that are sold to and marketed to prevent, among other things, pulmonary embolism via placement in the vena cava. One such Defendants' product, the Gunther Tulip Inferior Vena Cava Filter, is introduced into the vena cava via an 8.5 French coaxial introducer sheath system.

16. The Cook Gunther Tulip Filter is referred to herein as the Cook Filter.

17. Defendants sought Food and Drug Administration ("FDA") clearance to market the Cook Filter device and/or its components under Section 510(k) of the Medical Device Amendment.

18. On or about May 5, 2005, Defendants obtained FDA clearance to market the Cook Filter device and/or its components under section 510(k) of the Medical Device Amendment.

19. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device.

20. An IVC filter, like the Cook Filter, is a device designed to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

21. The inferior vena cava is a vein that returns blood to the. Heart from the lower portions of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach

the lungs they are considered "pulmonary emobli" or PE. PE presents a grave risk to human life and often result in death.

22. An IVC filter, like the Cook Filter, is designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

23. The Cook Gunther Tulip Filter is a retrievable filter.

24. Plaintiff is informed and thereupon alleges that the Cook Gunther Filter has four (4) anchoring struts for fixation and eight (8) independent secondary structs to improve self-centering and clot trapping.

25. On or about August 28, 2012, Plaintiff was implanted with a Cook Gunther Tulip Filter. This procedure occurred in Billings, Montana.

26. The device subsequently perforated through Plaintiff's vena cava, abutting her pancreas and duodenum and causing pain and life-threatening complications. This device failure was initially discovered during a CT scan at Mountain View Hospital in Las Vegas, Nevada on February 18, 2017.

27. Plaintiff was then evaluated by Bruce Hirschfeld, M.D. in Las Vegas, Nevada. Dr. Hirschfeld confirmed that at least two (2) of the struts from the Cook Filter migrated through the wall of the vena cava, abutting the pancreas and duodenum, with a mild tilt to the Cook Filter. Plaintiff was informed that risk of complications to the pancreas and duodenum, among others, is present. Plaintiff was further informed that, because the struts have migrated through the vena cava, removal of the Cook Filter is impossible. Any attempt at retrieval would result in an inability to remove it or definitive injury to the vena cava.

28. At all times relevant hereto, the Cook Filter was widely advertised and promoted by the Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.

29. At all times relevant hereto, Defendants knew its Cook Filter was defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

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30. Defendants failed to adequately disclose to physicians, patients or Plaintiff that its Cook Filter was subject to breakage, perforation, tilting migration or perforation and damage to the vena cava wall.

31. At all times relevant hereto, Defendants continued to promote the Cook Filter as safe and effective even though the clinical trials and/or other pre-market design and development that had been performed were not adequate to support long or short term safety and efficacy.

32. Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filter, as aforesaid.

33. The failure of the Cook Filter is attributable, in part, to the fact that the Cook Filter suffers from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

34. At all times relevant hereto, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo without fracturing, migrating, perforating, or tilting.

35. The Cook Filter was designed, manufactured, distributed, sold and/or supplied by the Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling and/or inadequate testing in light of Defendants' knowledge of the products failure and serious adverse events.

36. At all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

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CORPORATE/VICARIOUS LIABILITY

37. At all times herein mentioned, each of the Defendants was the agent, servant, partner, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

38. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

39. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for her damages.

40. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or within the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

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FIRST CAUSE OF ACTION

Strict Products Liability – Failure to Warn

41. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

42. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

43. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sale the device into the stream of commerce, Defendants knew or should have known the device presented a substantial and unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed, and sold the Cook Filter, which was implanted in Plaintiff, that the Cook Filter, inter alia, posed a significant and unreasonable risk of failure (fracture, migration, tilting, and perforation of the vena cava wall and internal organs) and resulting in serious injuries.

44. Therefore, Defendants had a duty to adequately warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

45. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Cook Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

46. No health care provider, including Plaintiff's health care providers, or patient, such as Plaintiff herself, would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

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47. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

48. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended and foreseeable manner.

49. Therefore, the Cook Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by Defendants.

50. As a direct and proximate result of the Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disfigurement and other losses, in an amount to be determined at trial.

51. Plaintiff has been required to retain the services of an attorney to prosecute this action and is entitled to reasonable attorneys' fees, interests, and costs incurred herein.

SECOND CAUSE OF ACTION

Strict Products Liability – Design Defects

52. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

53. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Cook Filter, including the one implanted in Plaintiff.

54. The Cook Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to the Cook Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

55. The Cook Filter implanted in Plaintiff was defective in design because it failed to perform in a manner reasonably expected by consumers given its nature and intended function.

56. The Cook Filter implanted in Plaintiff was defective in design in that its risks of harm exceeded its claimed benefits.

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57. Plaintiff and Plaintiff's health care providers used the Cook Filter in a manner that was reasonably foreseeable to Defendants.

58. Neither Plaintiff nor Plaintiff's health care providers could have, by the exercise of reasonable care, discovered the device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

59. As a direct and proximate result of the Cook Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disfigurement and other losses, in an amount to be determined at trial.

60. Plaintiff has been required to retain the services of an attorney to prosecute this action and is entitled to reasonable attorneys' fees, interests, and costs incurred herein.

THIRD CAUSE OF ACTION

Strict Products Liability – Manufacturing Defect

61. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

62. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook Filter that was implanted into Plaintiff.

63. The Cook Filter implanted into Plaintiff contained a condition, which Defendants did not intend, at the time it left Defendants' control and possession.

64. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

65. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

66. As a direct and proximate result of the Cook Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disfigurement and other losses, in an amount to be determined at trial.

67. Plaintiff has been required to retain the services of an attorney to prosecute this action and is entitled to reasonable attorney's fees, interest, and costs incurred herein.

FOURTH CAUSE OF ACTION

Negligence

68. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

69. At all times relevant to this action, Defendants were in the business of designing developing, setting specifications, manufacturing, marketing, selling, and distributing the Cook Filter.

70. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed, and sold the Cook Filter that was implanted in Plaintiff.

71. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Cook Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

72. Defendants knew or reasonably should have known that the Cook Filter was unreasonably dangerous or was likely to be unreasonably dangerous when used in its intended or reasonably foreseeable manner.

73. At the time of manufacture and sale of the Cook Filter starting in approximately 2005, Defendants knew or should have known that the Cook Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. Was designed and manufactured so as to present an unreasonable risk of the device perforating the vena cava wall and/or other internal organs;

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

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74. At the time of manufacture and sale of the Cook Filter, Defendants knew or should have known that using the Cook Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessel and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

75. Defendants knew or reasonably should have known that consumers of the Cook Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

76. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Cook Filter in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre- and post-sale, Plaintiff, Plaintiff's physicians, or the general health care community about the

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Cook Filter's substantially dangerous condition or about the facts making the product likely to be dangerous;

e. Failing to perform reasonable pre- and post-market testing of the Cook Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Cook Filter;

g. Advertising, marketing and recommending the use of the Cook Filter, while concealing and failing to disclose or warn of the dangerous known by Defendants to be connected with and inherent in the use of the Cook Filter;

h. Representing that the Cook Filter was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Cook Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Cook Filter so as to avoid the risk of serious harm associated with the use of the Cook Filter;

k. Advertising, marketing, promoting, and selling the Cook Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Cook Filter;

m. Failing to establish and maintain adequate post-market surveillance program.

77. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

78. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries,

economic loss, loss of enjoyment of life, disfigurement and other losses, in an amount to be determined at trial.

79. Plaintiff has been required to retain the services of an attorney to prosecute this action and is entitled to reasonable attorneys' fees, interests, and costs incurred herein.

FIFTH CAUSE OF ACTION

Breach of Implied Warranty of Merchantability

80. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

81. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Cook Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

82. At the time and place of the sale, distribution, and supply of the Defendants' Cook Filter System to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Cook Filter System was safe and effective for its intended and reasonably foreseeable use.

83. Defendants knew of the intended and reasonably foreseeable use of the Cook Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

84. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Cook Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

85. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Cook Filter was defective, unsafe, unreasonably

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dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Cook Filter from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the Cook Filter System was inadequately, improperly and inappropriately prepared and/or finished, causing the device to weaken and fail.

86. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether Cook Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Cook Filter was manufactured and sold.

87. Defendants placed the Cook Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Cook Filter was manufactured and sold.

88. Defendants breached their implied warranty because their Cook Filter was not fit for its intended use and purpose.

89. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disfigurement, and other losses, in an amount to be determined at trial.

90. Plaintiff has been required to retain the services of an attorney to prosecute this action and is entitled to reasonable attorneys' fees, interests, and costs incurred herein.

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SIXTH CAUSE OF ACTION

Negligent Misrepresentation

91. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

92. At all times relevant to this action, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Cook Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the Cook Filter;

b. The efficacy of the Cook Filter;

c. The rate of failure of the Cook Filter; and

d. The approved uses of the Cook Filter.

93. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Cook Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Cook Filter that was implanted in Plaintiff.

94. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Cook Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Cook Filter.

95. The foregoing representations and omissions by Defendants were in fact false. The Cook Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Cook Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

96. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Cook Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

97. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

98. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Cook Filter.

99. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Cook Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

100. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Cook Filter.

101. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants was the direct and proximate cause of Plaintiff's injuries as described herein.

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102. Plaintiff has been required to retain the services of an attorney to prosecute this action and is entitled to reasonable attorneys' fees, interests, and costs incurred herein.

SEVENTH CAUSE OF ACTION

Deceptive Trade Practice

103. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

104. At all relevant times, Defendants committed deceptive trade practices as defined in NRS Chapter 598, in that Defendants, and each of them:

a. Knowingly made a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease or a false representation as to the sponsorship, approval, status, affiliation or connections of a person therewith [NRS 598.0915(5)];

b. Knowingly made other false representations in a transaction affecting these plaintiffs [NRS 598.0915(15)];

c. Failed to disclose a material fact in connections with the sale or lease of goods or services [NRS 598.0923(2)]; and

d. Made assertions of scientific, clinical or quantifiable fact in an advertisement which would cause a reasonable person to believe that the assertions are true without factually objective scientific, clinical, or quantifiable evidence which substantiated the assertions at the time they were made [NRS 598.0925(1)(a)].

105. As a direct and proximate result of Defendants' commission of deceptive trade practices, Plaintiff suffered injury and damages as described above.

106. Plaintiff has been required to retain the services of an attorney to prosecute this action and is entitled to reasonable attorneys' fees, interests, and costs incurred herein.

PUNITIVE DAMAGES ALLEGATIONS

107. Plaintiff incorporates by this reference each and every allegation made in the preceding and ensuing paragraphs as if fully set forth herein.

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108. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, oppressive, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare and conscious indifference to the rights, safety and welfare of Plaintiff.

109. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Cook Filter was defective and unreasonably dangerous and had a substantial and unreasonably high probability of injury. Yet, Defendants failed to adequately:

a. Inform or warn Plaintiff or her health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Cook Filter from the market.

110. Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

111. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, and other losses, in an amount to be determined at trial.

DEMAND FOR JURY TRIAL

112. Plaintiff hereby demands a trial by jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for judgment against Defendants, and each of them, as follows:

1. For special damages according to proof at the time of trial;

2. For general damages according to proof at the time of trial;

3. For punitive damages;

4. For attorneys' fees and costs of suit incurred herein;

5. For pre-judgment and post-judgment interest, as allowed by law; and

6. For such other and further relief as is appropriate under the circumstances.

Dated this 12th day of February, 2019.

CHRISTIANSEN LAW OFFICES

By _____

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